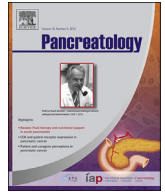




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Original article

A standardized method for endoscopic necrosectomy improves complication and mortality rates

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ABSTRACT

Objectives: Endoscopic necrosectomy is effective in the treatment of walled-off necrosis (WON), and is preferred to surgical approaches, however complication and mortality rates remain high with few centers regularly employing the technique. Lack of a standardized approach may also contribute to these limitations.

Methods: Prior to the study, a multidisciplinary team applied standardized care assessment and management plan principles to develop and optimize a systematic approach for the management of WON. Preoperative, postoperative, and endoscopic management were standardized. Patient preparation, room set-up, technical features (EUS-guidance, cold-access with balloon dilation, fragmentation of necrosis on the initial procedure, antibiotic lavage, double pigtail stents), and discontinuation of PPIs to encourage auto-digestion of necrosis were included. This study employed a consecutive prospective clinical registry to assess the clinical outcomes of this standardized approach.

Results: 60 consecutive patients underwent 1.58 ± 0.1 necrosectomies, with debridement accomplished on the initial procedure in 98.3%. 39 patients (65%) required only one session. Clinical resolution occurred in 86.7%, with radiologic confirmation. Percutaneous drainage was required in 8 patients during follow-up, and 4 of these later required surgery. Serious adverse events occurred in 3.3% of patients, and there was no mortality.

Conclusions: The standardized technique employed in this series was associated with lower rates of adverse events, morbidity, and mortality than prior large series. Use of a systematic approach, and integrating elements of this method may improve the risk profile of endoscopic necrosectomy and allow broader adoption.

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Introduction

Acute pancreatitis is responsible for over 270,000 admissions annually [1]. Approximately 20% of cases are complicated by

pancreatic necrosis, and 30% of these become infected [2,3]. Infected necrosis and associated systemic illness have a mortality rate approaching 100% without procedural intervention [4,5]. Although outcomes have improved in recent years due to earlier recognition, improved supportive care, and development of less invasive therapeutic modalities, considerable variability in patient management persists [6,7].

The pancreatic and peripancreatic fluid collections associated with acute pancreatitis have been better classified in recent years. Walled-off necrosis (WON) is a well-demarcated, organized collection of necrotic tissue [8]. Given the morbidity of pancreatic surgery, the preferred management strategy for

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WON has been studied intensely, and has changed with study results over time. Open surgical necrosectomy, and more recently minimally invasive surgical necrosectomy, are associated with complication rates as high as 72% [9,10]. Subsequent studies, including the randomized PANTER trial, have demonstrated that a step-up approach involving initial percutaneous catheter drainage (PCD), followed by minimally invasive surgical necrosectomy if needed, is associated with less morbidity than initial open surgical necrosectomy [11]. Direct endoscopic necrosectomy (DEN) is the most recent therapeutic modality to be employed in the management of WON. This technique allows drainage and endoscopic debridement of necrotic tissue through the gastric or duodenal wall [12]. DEN has demonstrated a higher resolution rate for WON than endoscopic drainage alone (88% versus 45%), underscoring the importance of debridement of semi-solid necrotic material [13]. In the PENGUIN trial, DEN resulted in less new-onset multiorgan failure and a lower major complication rate than surgical necrosectomy [14]. Furthermore, a recent analysis comparing DEN with the step-up approach found a lower need for antibiotic initiation, less new pulmonary failure, less new endocrine insufficiency, shorter length of stay, and lower health care utilization with DEN [15].

Unfortunately, while DEN has been shown to have lower morbidity and mortality than surgical approaches, there remains a substantial risk of adverse events and mortality, as well as considerable variability in performance of the procedure. Notably, larger series report a mortality of up to 7.5% and an adverse event rate of 14–26% [13,16].

Lack of a standard approach to this complex procedure may contribute to these concerns. Procedural variability is not only evident when comparing studies, but is also present within most published series. Within a given center, and even for a single operator, there is often a lack of consistency regarding technical approach to the procedure. Furthermore, due to the large variety of techniques, and relative small number of procedures in the literature, a direct comparison of methods has not been possible. Studies have reported blind entry using electrosurgical incision into a

visible bulge in the stomach or duodenum, endoscopic ultrasound (EUS) guided access, electrocautery for hot access under EUS-guidance, cold access applying balloon dilation over a wire, use or no use of lavage solutions, and some studies have reported initial drainage followed by debridement days to weeks after the initial procedure versus debridement at the index procedure [14,16–19]. Published studies have also reported a range of debridement sessions, from daily to every few days, with 2.5–7 sessions in total [17,16,20].

In order to address the relatively high adverse event rate and mortality risk associated with DEN, each component of the procedure was analyzed to optimize efficiency, maximize safety, and minimize adverse events. As a prelude to this study, various DEN procedural details were considered and modified over time based on clinical experience and the feedback of a multidisciplinary clinical management group consisting of medical pancreatologists, therapeutic endoscopists, radiologists, and surgeons. Ultimately, a standardized care and assessment management plan (SCAMP) for DEN was developed. In this report, we describe the clinical outcomes of this standardized method for DEN in the treatment of WON.

Materials & methods

Patients & study design

This study was performed using a consecutive prospective clinical registry. Institutional Review Board approval was obtained. Inclusion criteria were diagnosis of acute pancreatitis based on the Atlanta classification and presence of symptomatic WON. All patients had computed tomography (CT) of the abdomen and pelvis within 10 days prior to the procedure. Charlson comorbidity index was calculated at the time of first procedure (Fig. 1). The following data were collected: baseline demographics, etiology of pancreatitis, time interval between onset of pancreatitis and first endoscopic treatment, radiologic features of the collections, microbiologic culture data, procedure characteristics, number and

Charlson Comorbidity Index Scoring System

Score	Condition
1	Myocardial infarction (history, not ECG changes only)
	Congestive heart failure
	Peripheral vascular disease (includes aortic aneurysm ≥ 6 cm)
	Cerebrovascular disease: CVA with mild or no residua or TIA
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Peptic ulcer disease
	Mild liver disease (without portal hypertension, includes chronic hepatitis)
	Diabetes without end-organ damage (excludes diet-controlled alone)
	2
Moderate or severe renal disease	
Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes)	
Tumor without metastases (exclude if >5 y from diagnosis)	
Leukemia (acute or chronic)	
Lymphoma	
3	Moderate or severe liver disease
	6
AIDS (not just HIV positive)	

NOTE. For each decade > 40 years of age, a score of 1 is added to the above score.

Abbreviations: ECG, electrocardiogram; CVA, cerebrovascular accident; TIA, transient ischemic attack; AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

Fig. 1. Charlson comorbidity index scoring system. Reprinted from American Journal of Kidney Diseases, 32(2), Fried L, Bernardini J, Piraino B, Charlson Comorbidity Index as a Predictor of Outcomes in Incident Peritoneal Dialysis Patients, 338, 2001, with permission from Elsevier.

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